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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,242	06/24/2003	Ye Fang	SP02-143	1181
22928	7590	08/10/2006	EXAMINER	
CORNING INCORPORATED			YANG, NELSON C	
SP-TI-3-1				
CORNING, NY 14831			ART UNIT	PAPER NUMBER

1641

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/602,242		FANG ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Nelson Yang		1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,4,5,9-18 and 42-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,5,9-18 and 42-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

### ***Rejections Withdrawn***

2. Applicant's arguments, filed May 22, 2006, with respect to the rejections under 35 U.S.C. 103(a) have been fully considered and are persuasive. The rejection of 1, 2, 4, 5, 9-18, 42-61 under 35 U.S.C. 103(a) has been withdrawn.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, 4, 5, 17, 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Pidgeon [US 4,931,498].

With respect to claim 1, Pidgeon teaches supports having a pellicular coating formed from a polyamine, such as polyethylene (column 6, lines 15-30) upon which biological membranes are immobilized (column 6, lines 32-50). Pidgeon teaches that the membranes can remove endotoxins from contaminated protein samples (column 13, lines 1-5).

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5. With respect to claim 2, Pidgeon teaches that the membrane can remove endotoxins from contaminated protein samples (column 13, lines 1-5), which would require a toxin binding moiety.

6. With respect to claims 4, 5, Pidgeon teaches that the membranes can comprise gangliosides (column 7, lines 1-6).

7. With respect to claim 17, the support may be porous (column 5, lines 55-58).

8. With respect to claim 18, the supports can be particulate support structures (particles) (column 5, lines 54-55).

9. Claims 57, 60, 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamazaki et al [US 6,699,719].

With respect to claims 57, 60, 61, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al further teach a film of polyacrylamide coupled to 3-methacryl-oxypropyl-trimethoxy-silane on the surface of the support (column 18, lines 2-28).

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 2, 4-5, 9-16, 18, 42-50, 52, 54, 56, 58, 59, are rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Pidgeon [US 4,931,498].

With respect to claims 1, 42, 52, 54, 56, 58, 59, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al does not teach membranes deposited on an amine-presenting molecule.

Pidgeon, however, teaches a surface coated with a layer of a polyamine such as polyethylenimine (PEI) for attaching membranes (column 6, lines 32-50). Pidgeon further teach that functional groups such as PEI form covalent bonds with amphiphilic compounds and allow for mechanically stable structures.

Therefore, it would have been obvious to one of ordinary skill in the art for the support to have a layer of PEI in the method of Yamazaki et al to bind membranes, as suggested by Pidgeon, in order to produce mechanically stable support structures for binding membranes.

12. With respect to claims 2, 4-5, Yamazaki et al teach that the arrayed membranes comprise gangliosides that bind to cholera toxin (column 31, example 8).

13. With respect to claim 9, the arrays are arranged into corrals of 500 microns<sup>2</sup> (column 31, lines 45-50).

14. With respect to claims 10-12, 14-15, 43, 44, Yamazaki et al teach that the toxin is labeled with Texas Red (column 64-66), the and the fluorescence microscope detects the corrals with

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bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

15. With respect to claim 13, Yamazaki et al teach a competitive assay between a fluorescent antagonist (column 34, lines 65-67), and a receptor sensitive antagonist (column 35, lines 1-5).

16. With respect to claim 16, the substrate can be a silicon wafer (column 12, lines 20-26).

17. With respect to claim 18, Yamazaki et al teach that the substrate can comprise well plate having surface detector array devices at the bottom of the wells (column 5, lines 18-20).

18. With respect to claim 45, Yamazaki et al teach that the arrays are washed after incubation with the toxin (column 31, line 66 – column 32, line 4).

19. With respect to claim 46, Yamazaki et al teach that the arrays are incubated with cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8). Therefore, a decrease in the green fluorescence indicates binding of cholera toxin to ganglioside GM1.

20. With respect to claims 47-48, Yamazaki et al teach that measurement may be performed using capacitive detection or impedance analysis (column 18, lines 43-46).

21. With respect to claims 49-50, Yamazaki et al teach that the sample is cholera toxin which binds to ganglioside GM1 (column 31, lines 62-65). The fluorescence microscope detects the corrals with bound cholera toxin as red (column 32, lines 1-10) while the non-bound corrals remain green (column 32, lines 5-8).

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22. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Pidgeon [US 4,931,498], and further in view of Pluskal et al [US 5,004,543].

With respect to claim 17, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines 65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al do not teach a microporous support.

Pluskal et al, however, teach a charge-modified, hydrophobic microporous membrane and further teaches that the membrane exhibits a combination of ionic and hydrophobic properties, rendering them highly effective for macromolecular adsorption applications under a variety of conditions (column 2, lines 35-46).

Therefore, it would have been obvious to one of ordinary skill in the art to have a charge-modified, hydrophobic microporous membrane as the support in the method of Yamazaki et al and Pidgeon, as suggested by Pluskal et al, as the membrane is highly effective for macromolecular adsorption applications under a variety of conditions.

23. Claims 51, 53, 55, are rejected under 35 U.S.C. 103(a) as being unpatentable Yamazaki et al [US 6,699,719] in view of Pidgeon [US 4,931,498] and further in view of Patton [US 4,933,285].

With respect to claims 51, 53, 55, Yamazaki et al teach biosensor arrays comprising substrates with a plurality of distinct membranes of bilayer regions (column 7, lines 40-50). Assays are performed by incubating the arrays with a cholera toxin solution (column 31, lines

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65-67), followed by washing (column 32, lines 1-3), and imaged with a fluorescence microscope (column 32, lines 5-10). Yamazaki et al do not teach a coating of  $\gamma$ -aminopropylsilane on the support.

Patton, however, teaches substrates comprising coatings of  $\gamma$ -aminopropylsilane (column 4, lines 15-20). Patton further teaches that this produces solid phases that serve to anchor reaction products to a solid phase, while permitting the unreacted reagents to be removed (column 3, lines 35-42). Therefore, this would allow Yamazaki et al to anchor lipid membranes to the support that have reacted with the  $\gamma$ -aminopropylsilane, while removing unbound lipid membranes.

Therefore, it would have been obvious to one of ordinary skill in the art to have a coating of  $\gamma$ -aminopropylsilane to anchor lipid membranes to the support that have reacted with the  $\gamma$ -aminopropylsilane, while removing unbound lipid membranes.

### ***Response to Arguments***

24. Applicant's arguments with respect to claims 1, 2, 4, 5, 9-18, 42-61 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

25. No claims are allowed

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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